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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MEHTA, ASHWIN D	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/972,805	CHANDLER ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-34,41-53 and 61-380* is/are pending in the application.

4a) Of the above claim(s) *41-80,101-120,141-200,221-340 and 361-380* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-34,81-100,121-140,201-220 and 341-360* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *100501 & 7072003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 29-34, 81-100, 121-140, 201-220, and 341-360 in the paper submitted March 1, 2004 is acknowledged. The traversal is on the ground(s) that Applicants believe that the burden of searching the various groups would not be undue. This is not found persuasive because the various groups involve the searching of numerous, genetically distinct corn plants. The number of plants to be searched creates an undue burden.

The requirement is still deemed proper and is therefore made FINAL. Non-elected claims 41-80, 101-120, 141-200, 221-340, and 361-380 are withdrawn from consideration.

Information Disclosure Statement

2. The information disclosure statement filed November 16, 2001 fails to comply with 37 CFR 1.98(a)(2). Copies of the references listed in the IDS have not been received. The IDS has been placed in the application file, but the information referred to therein has not been considered.

Specification

3. Figures 6 and 24 contain multiple views that are labeled with letters. However, the brief descriptions of those figures in the specification do not recite those labels, as required by 37 CFR 1.74.

Claim Objections

4. Claims 87, 90, 127, 130, 140, 207, 210, 220, 347, 350, and 360 are objected to for the following reasons:

Claim 87, 90, 127, 130, 207, 210, 347, and 350 are objected to under 37 CFR 1.75(c) for failing to limit the subject matter of a previous claim. Claim 87, for example, is drawn to a seed produced from the plant of claim 82. Claim 82, however, does not encompass any seed. Claims 90, 127, 130, 207, 210, 347, and 350 are objected to for the same reasons.

Claims 140, 220, and 360 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form.

Claim 140 requires the hybrid corn plant of claim 139 to be an F1 generation plant. However, the hybrid plant of claim 139 is an F1 generation plant. The hybrid plant of claim 139 is produced in a process in which only one cross is performed. Claim 140 therefore does not further limit the claim from which it depends. Claims 220 and 360 do not limit the claims from which they depend for the same reason.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 29-34, 81, 83, 85, 86, 91, 94, 100, 125, 126, 131, 134, 201, 205, 206, 211, 214, 345, 346, 351, 354 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 29: the recitation, "at least a two to three-fold increase in expression" renders the claim indefinite. The lower level of increase in transgene expression is not clear. If the mutation(s) causes a two fold increase in expression, as opposed to a two to three fold increase, is the plant encompassed by the claim? The metes and bounds of the claim are unclear.

In claims 81 and 201: the recitation, "designated genotypically designated" in line 1 renders the claims indefinite. It is not exactly clear what is meant by this recitation.

In claims 83, 85, 125, 205, 345: the recitation, "genetical" in line 1 of claim 83 and "genetical characteristics" in line 1 of the claims 85, 125, 205, and 345 render the claims indefinite. It is not exactly clear what is meant by "genetical" in the context of the claimed invention. Is the recitation referring to genotype only, both genotype and phenotype, or phenotype only, etc.?

In claims 86, 126, 206, 346: the recitation "An essentially homogeneous population of corn plants produced by growing the seed of the corn plant of claim 82 (or 122, or 202, or 342)" in lines 1-2 renders the claims indefinite. The recitation, 'essentially homogeneous", in claim 86 for example, indicates that more than one variety of corn plant can be produced from the seed of the plant of claim 82. The seeds of the plant of claim 82, however, can only produce one variety of plant, that produced from seed designated "rmr2-1" and deposited with the ATCC under Accession Number PTA-3956. Claim 82 does not mention any other type of plant. It is not

clear, because of the recitation, "essentially homogeneous", if the population contains different varieties of plants, or only plants produced from rmr2-1 seed. Claims 126, 206, and 346 are indefinite for the same reason.

In claim 91, 131, 211, and 351: the claims recite the limitation, "The tissue culture of regenerable cells." There is insufficient antecedent basis for this limitation in the claims. It is suggested that the article "The" in line 1 of each claim be replaced with --A--.

In claims 91, 94, 131, 134, 211, 214, 351, and 354: the recitation, "capable of expressing" in line 2 of the claims renders them indefinite. The recitation does not make clear if the plant actually expresses the characteristics, or when or under what conditions the characteristics are expressed. The recitation can be interpreted to indicate that, while the plant has the capacity to express the characteristics, for some reason it may not. Certain characteristics of a plant are expressed only at certain times of its life cycle, and are incapable of being expressed at other times. The colors of flower parts such as silks, or fruit parts such as husks, are examples. The promoters of many genes conferring traits require a transcription factor to become active. Is a plant that has such a gene, but not the transcription factor, considered "capable of expressing" that gene, and the characteristics associated with that gene, and is such a plant encompassed by the claims? Furthermore, traits such as plant height or yield are environmentally influenced. A particular value for plant height or seed yield observed in one growing environment may not be observed in another environment. It is suggested that the recitation "the tissue regenerates plants capable of expressing" in claims 91, 131, 211, and 351 be replaced with --plants, when regenerated from said tissue culture, have--. It is suggested that the recitation, "is capable of expressing" in claims 94, 134, 214, and 354 be replaced with --having--.

In claim 100: the recitation, "The hybrid corn plant of claim 98" renders the claim indefinite. Claim 98 is directed to seed, not a plant. Note that if claim 100 were dependent on claim 99, that the claim would then be objected to for not further limiting claim 99, since the hybrid corn plant of claim 99 is a F1 hybrid corn plant. See the objection to claims 140, 220, and 360, above.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 29-34, 81-100, 121-140, 201-220, and 341-360 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any mutant corn plant comprising one or more mutations that cause at least a two to three-fold increase in the expression of a transgene compared to expression of the transgene in a non-mutant transgenic corn plant; progeny seed of said mutant plant; a tissue culture of regenerable cells of said mutant plant; or wherein said mutant plant is selected from the group consisting of mop1-2, Mop2-1, rmr1-1, and rmr2-1; corn seed genotypically designated rmr2-1, Mop2-1, Mop1-2EMS, or rmr1-1; a corn plant produced from said seed; a corn plant having all of the genetical, phenotypic, and morphological characteristics of said plant; progeny seed produced from said plant; a plant produced from said

progeny seed, and a seed produced from that plant; a tissue culture of regenerable cells from plant rmr2-1, Mop2-1, Mop1-2EMS, or rmr1-1; a corn plant regenerated from said tissue culture; a process of producing corn seed comprising self-pollinating plant rmr2-1, Mop2-1, Mop1-2EMS, or rmr1-1 or crossing one of said plants with a second plant; hybrid corn seed and plant produced from said cross.

The specification indicates paramutation involves an interaction between two alleles that leads to a heritable reduction in expression of one of the alleles. Alleles sensitive to reduced expression are "paramutable," and alleles inducing the change, "paramutagenic." Following paramutation, sensitive alleles are termed "paramutant" (page 20, paragraph 00116). The specification indicates that mutants defective in paramutation were tested for their effect on transgene silencing. Transgenic plants were produced that comprised various "B" transgenes, which encodes a transcription factor that activates the anthocyanin biosynthetic pathway. Expression of B gives rise to purple pigmentation. One transgenic corn line carries a construct comprising a 35S driving expression of B-I. Expression of this transgene was not phenotypically detectable in the plant, but was detectable in aleurone layer of seeds. Another transgenic corn line carries a construct comprising the "B-Boliva" promoter fused to B-I. The original transgenic line expressed the construct in the plant and aleurone layer of the seed, but plant pigmentation was lost in subsequent generations (page 90, paragraph 00323). The specification discusses experiments in which four mutant plants defective in paramutation, Mop1-1, Mop2-1, rmr1-1, and rmr2-1, were crossed with the transgenic B-I lines, and resulted in progeny plants in which silencing of B was lifted. The activation of the B transgene occurred at the transcriptional level in the presence of the Mop1-1 and rmr2-1 mutations. These mutations can heritably

activate the transgene, such that the transgene remains active when the mutation is segregated away (pages 90-95, Example 5).

Claim 29 encompasses a broad genus of plants: any mutant corn plant, comprising any kind of mutation in any gene, wherein the mutation(s) cause at least a two-three fold increase in transgene expression compared to transgene expression in a non-mutant plant. However, the specification only discusses four mutant plants, Mop1-1, Mop2-1, rmr1-1, and rmr2-1, that have this phenotype. These plants are not representative of other mutant corn plants of the genus, as their structures can differ in any manner from Mop1-1, Mop2-1, rmr1-1, and rmr2-1. The specification does not correlate any other mutation to the characteristic of causing an increase transgene expression. Further, claim 34 recites the limitation that the mutant corn plant can be mop1-2. However, the specification does not make any mention of this mutation having the ability to cause an increase in transgene expression.

The specification indicates that chemical mutagenesis using ethyl methanesulfonate (EMS) was conducted to produce mutants defective in paramutation. The EMS induced mutation, ems-96, refers to the rmr2-1 locus; ems-136 designates rmr1-1; ems-240 designates Mop1-2EMS (pages 63-71, paragraphs 00257-00272). A dominant mutation, Mop2-1, was also identified (page 81, paragraph 00296 to page 85, paragraph 00307). The specification indicates that seeds of the mutant plants have been deposited with the ATCC (pages 33-34).

However, while the specification discusses genetic analyses of the mutant alleles of the elected plants, descriptions of other genotypic, morphological, and/or physiological characteristics of the claimed plants are not provided. A deposit of the seed of corn plants rmr1-1, rmr2-1, mop2-1, and mop1-2EMS would satisfy the written description requirement for these

seeds, and the specification does indicate that such a deposit has been made with the ATCC. However, other deposit requirements of 37 CFR 1.801-1.809 have not been met. Satisfaction of these requirements (outlined below) will overcome the rejection for the claims directed to these seeds and the plants produced by growing them.

The specification indicates that seed of inbred corn plant LIZL5, and hybrid seed produced by crossing a LIZL5 plant with any other corn plant, are essential to the operation and function of the claimed invention. A search of seed of inbred corn plant LIZL5 indicates that it is novel and unobvious.

A review of the language of claims 30, 31, 87-90, 98-100, 127-130, 138-140, 207-210, 218-220, 347-350, and 358-360 indicates that the claims are drawn to a genus that comprises any and all hybrid corn seeds, and the hybrid corn plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing the plant of claim 29, 81, 121, 201, or 341 with any second corn plant. Claims 89-90, 129-130, 209-210, and 349-350 are drawn to seeds and plants of the following generation. Variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles. As a result, the complete genomic structure of each hybrid, and therefore the genotypic, morphological and physiological characteristics expressed by each hybrid would differ.

The specification discusses the inheritance of paramutation from the plants that have been deposited with the ATCC. However, the specification does not describe all of the genotypic, phenotypic, and morphological characteristics of the claimed hybrid corn seeds or plants. There is no evidence on the record of a relationship between the structure of the complete genome of

the claimed hybrid seeds and plants with the complete genome of other hybrids. Hybrids produced by crossing the corn plants deposited with the ATCC would produce plants that do not express the same traits. The descriptions of the inheritance of paramutation of progeny corn plants in the specification do not provide any information concerning the other morphological and physiological characteristics of those plants or of other hybrid seeds or plants. In view of these considerations, a person of skill in the art would not have viewed the teachings of the specification as sufficient to show that the Applicant was in possession of the claimed genus of hybrid seeds and plants produced therefrom.

7. Claims 34, 81-100, 121-140, 201-220, and 341-360 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards any mutant corn plant comprising one or more mutations that cause at least a two to three-fold increase in the expression of a transgene compared to expression of the transgene in a non-mutant transgenic corn plant, wherein said mutant plant is selected from the group consisting of mop1-2, Mop2-1, rmr1-1, and rmr2-1; corn seed genotypically designated rmr2-1, Mop2-1, Mop1-2EMS, or rmr1-1; a corn plant produced from said seed; a corn plant having all of the genetical, phenotypic, and morphological characteristics of said plant; progeny seed produced from said plant; a plant produced from said progeny seed, and a seed produced from that plant; a tissue culture of regenerable cells from

plant rmr2-1, Mop2-1, Mop1-2EMS, or rmr1-1; a corn plant regenerated from said tissue culture; a process of producing corn seed comprising self-pollinating plant rmr2-1, Mop2-1, Mop1-2EMS, or rmr1-1 or crossing one of said plants with a second plant; hybrid corn seed and plant produced from said cross.

The specification on pages 32-35 indicates that seeds of the mutant corn plants mop1-2, rmr1-1, rmr2-1, Mop2-1, and Mop1-2EMS have been deposited with the ATCC. However, the specification does not indicate that all of the requirements of deposit, outlined in 37 CFR 1.801-1.809, have not been satisfied. Since the claimed seeds and plants are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seeds are not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence. Since the claimed seeds are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seeds in each occurrence and it is not apparent if such seeds are readily available to the public.

If the seeds were deposited under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicants, or a statement by an attorney of record over his or her signature and registration number, must also be submitted, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent. A minimum

deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must by maintained. See 37 CFR 1.801-1.809.

If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 29 and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Chandler et al. (Plant Mol. Biol., June 2000, Vol. 43, pages 121-145).

The claims are broadly drawn towards any mutant corn plant comprising one or more mutations that cause at least a two to three-fold increase in the expression of a transgene compared to expression of the transgene in a non-mutant transgenic corn plant, or wherein said mutant plant is selected from the group consisting of mop1-2, Mop2-1, rmr1-1, and rmr2-1.

Chandler et al. teach mutant corn plants mop1-2 and rmr1-1 (pages 137-138). The properties of causing at least a two to three-fold increase in the expression of a transgene as compared to the expression of the transgene in a non-mutant transgenic corn plant is inherent to the plants taught by the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler et al. (Plant Mol. Biol., June 2000, Vol. 43, pages 121-145).

The claims are broadly drawn towards any mutant corn plant comprising one or more mutations that cause at least a two to three-fold increase in the expression of a transgene compared to expression of the transgene in a non-mutant transgenic corn plant; or seed from said

mutant plant; or a tissue culture of regenerable cells of said mutant plant; or wherein the increase in transgene expression in said mutant plant is detectable by RNA analysis; or wherein said mutant plant is selected from the group consisting of mop1-2, Mop2-1, rmr1-1, and rmr2-1.

Chandler et al. is discussed above.

Chandler et al. do not teach seeds of the mutant plants, tissue cultures of regenerable cells, or RNA analysis of transgene expression.

It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to produce tissue cultures of regenerable cells of the mutant plants of Chandler et al., or to cross the mutant plants of Chandler et al., either to themselves or with other corn plants, to produce seeds and plants of the following generation. One would obviously have been motivated to do so for the purpose of propagation. It also would have been obvious to measure the increase in transgene expression by RNA analysis. The means of detecting the increase in transgene expression depends on one's desired end and amounts to an optimization of process parameters.

10. Claims 29-34, 81-100, 121-140, 201-220, and 341-360 are rejected. Non-elected claims 41-80, 101-120, 141-200, 221-340, and 361-380 are withdrawn from consideration.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 8, 2004

Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638